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APPLICATION NO.	FILING DATE	FIRST NAMED INVENTOR	ATTORNEY DOCKET NO.	CONFIRMATION NO.
10/676,715	10/01/2003	Cordula Hopmann	DEAV2002/0066 US NP	2948

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ROSS J. OEHLER  
AVENTIS PHARMACEUTICALS INC.  
ROUTE 202-206  
MAIL CODE: D303A  
BRIDGEWATER, NJ 08807

EXAMINER

OH, TAYLOR V

ART UNIT	PAPER NUMBER
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1625

DATE MAILED: 11/16/2004

Please find below and/or attached an Office communication concerning this application or proceeding.

## Office Action Summary

**Application No.**

10/676,715

**Applicant(s)**

HOPMANN ET AL.

**Examiner**

Taylor Victor Oh

**Art Unit**

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-- The MAILING DATE of this communication appears on the cover sheet with the correspondence address --  
Period for Reply

A SHORTENED STATUTORY PERIOD FOR REPLY IS SET TO EXPIRE 3 MONTH(S) FROM THE MAILING DATE OF THIS COMMUNICATION.

- Extensions of time may be available under the provisions of 37 CFR 1.136(a). In no event, however, may a reply be timely filed after SIX (6) MONTHS from the mailing date of this communication.
- If the period for reply specified above is less than thirty (30) days, a reply within the statutory minimum of thirty (30) days will be considered timely.
- If NO period for reply is specified above, the maximum statutory period will apply and will expire SIX (6) MONTHS from the mailing date of this communication.
- Failure to reply within the set or extended period for reply will, by statute, cause the application to become ABANDONED (35 U.S.C. § 133). Any reply received by the Office later than three months after the mailing date of this communication, even if timely filed, may reduce any earned patent term adjustment. See 37 CFR 1.704(b).

**Status**

- 1) ☒ Responsive to communication(s) filed on 07 June 2004.
- 2a) ☐ This action is **FINAL**. 2b) ☒ This action is non-final.
- 3) ☐ Since this application is in condition for allowance except for formal matters, prosecution as to the merits is closed in accordance with the practice under *Ex parte Quayle*, 1935 C.D. 11, 453 O.G. 213.

**Disposition of Claims**

- 4) ☒ Claim(s) 1-11 is/are pending in the application.
- 4a) Of the above claim(s) \_\_\_\_\_ is/are withdrawn from consideration.
- 5) ☐ Claim(s) \_\_\_\_\_ is/are allowed.
- 6) ☒ Claim(s) 1-11 is/are rejected.
- 7) ☐ Claim(s) \_\_\_\_\_ is/are objected to.
- 8) ☐ Claim(s) \_\_\_\_\_ are subject to restriction and/or election requirement.

**Application Papers**

- 9) ☐ The specification is objected to by the Examiner.
- 10) ☐ The drawing(s) filed on \_\_\_\_\_ is/are: a) ☐ accepted or b) ☐ objected to by the Examiner.  
Applicant may not request that any objection to the drawing(s) be held in abeyance. See 37 CFR 1.85(a).  
Replacement drawing sheet(s) including the correction is required if the drawing(s) is objected to. See 37 CFR 1.121(d).
- 11) ☐ The oath or declaration is objected to by the Examiner. Note the attached Office Action or form PTO-152.

**Priority under 35 U.S.C. § 119**

- 12) ☒ Acknowledgment is made of a claim for foreign priority under 35 U.S.C. § 119(a)-(d) or (f).
- a) ☒ All b) ☐ Some \* c) ☐ None of:
1. ☒ Certified copies of the priority documents have been received.
  2. ☐ Certified copies of the priority documents have been received in Application No. \_\_\_\_\_.
  3. ☐ Copies of the certified copies of the priority documents have been received in this National Stage application from the International Bureau (PCT Rule 17.2(a)).

\* See the attached detailed Office action for a list of the certified copies not received.

**Attachment(s)**

- |   |   |
|---|---|
| 1) <input type="checkbox"/> Notice of References Cited (PTO-892)  | 4) <input type="checkbox"/> Interview Summary (PTO-413)<br>Paper No(s)/Mail Date. _____ |
| 2) <input type="checkbox"/> Notice of Draftsperson's Patent Drawing Review (PTO-948)  | 5) <input type="checkbox"/> Notice of Informal Patent Application (PTO-152)             |
| 3) <input checked="" type="checkbox"/> Information Disclosure Statement(s) (PTO-1449 or PTO/SB/08)<br>Paper No(s)/Mail Date <u>2/6/04 or 6/7/04</u> . | 6) <input type="checkbox"/> Other: _____  |

The Status of Claims:

Claims 1-11 are pending.

Claims 1-11 have been rejected.

DETAILED ACTION

1. Claims 1-11 are under consideration in this Office Action.

Priority

2. It is noted that the examiner has been acknowledged that a foreign priority document, EPO 02022095.0 (10/02/2002) is in the file.

Drawings

3. None.

***Claim Objections***

Claim 7 is objected to because of the following informalities: the phrase "a physiologically tolerated salts" is recited. The examiner recommends that the plural term "salts" should be changed to the singular term "salt". Appropriate correction is required.

The following is a quotation of the first paragraph of 35 U.S.C. 112:

The specification shall contain a written description of the invention, and of the manner and process of making and using it, in such full, clear, concise, and exact terms as to enable any person skilled in the art to which it pertains, or with which it is most nearly connected, to make and use the same and shall set forth the best mode contemplated by the inventor of carrying out his invention.

Claim 8 is rejected under 35 U.S.C. 112, first paragraph, as failing to comply with the enablement requirement. The claim(s) contains subject matter which was not described in the specification in such a way as to enable one skilled in the art to which it pertains, or with which it is most nearly connected, to make and/or use the invention.

The specification mentions that it is possible to treat various mental diseases, such as Alzheimer's Disease (AD), Parkinson's disease, Huntington disease, stroke, psychosis or depression by using inhibitors of the spinophilin-PP1 complex and /or JNK3 . The JNK pathway leading to c-Jun phosphorylation may play a casual role in apoptosis of isolated of isolated primary embryonic neurons and of multiple neuronal cell lines, and also the spinophilin plays an important role in regulating the phosphorylation states of glutamate receptors in dendrites by anchoring PP1 in the proximity of these receptors; therefore, dysregulation of glutamate receptors may lead to a long term depression , according to Jiang Feng et al (Proc. Natl. Acad. Sci. USA 2000, 97 , p. 9287-9292).

However, not only the inhibitors of the spinophilin, but also the beta-amyloid protein may induce Alzheimer's Disease (AD). Many scientists and medical doctors are in search for finding the main causative factors in order to treat the Alzheimer's Disease. For example, according to Meda et al (Nature 374,647 (1995) and Larner (Neurosci. Res. Commun. 20 , 147 (1997),  $\beta$ -amyloid peptide was shown to exert direct

toxic effects on neurons and to inhibit neurite growth in vitro. Thus, therapeutic approaches that can modulate  $\beta$ A peptide toxicity have been hypothesized to represent important methods for controlling the onset of AD. It is postulated that if neuronal cells can be protected from  $\beta$ A peptide/senile plaque-induced toxicity, the onset of AD may be delayed ; furthermore, St. George-Hyslop et al (Nature 400, 116 (1999) indicates that an anti- $\beta$ A protein antibody was shown to clear senile plaques and protect mutant PDAPP mice from the onset of AD. From this, the generation of reactive oxygen intermediates through oxidative stress caused by  $\beta$ A peptide has been suggested to be the major pathway of  $\beta$ A peptide-induced cytotoxicity.

So far, they do not know for sure what caused people to have the AD or the other types of mental diseases. The induced beta-Amyloid protein toxicity and the activation of this JNK pathway and/ or the unregulation of glutamate receptors may be the outcomes of the AD, but not the underlying cause of the AD. Therefore, the specification falls short because data essential for treating mental diseases, such as Alzheimer's Disease , Parkinson's disease, Huntington disease, stroke, psychosis or depression, whether all the mental diseases are induced only by the activation of this JNK pathway and the irregularation of glutamate receptors or not, are not described in the specification.

In claim 8, the phrase "for the treatment or prevention of Alzheimer's Disease , Parkinson's disease, Huntington disease, stroke, psychosis or depression" is recited. However, the specification does not describe how to prevent the above mental

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diseases and also, there are no showings of any evidence for "preventing those diseases" at the same time. Furthermore, the contemporary knowledge of the art does not teach "how to prevent" for all the alleged mental diseases. If we could prevent all the possible permutations and combinations of the above, nobody would be sick. In addition, more than routine experimentation is involved. See In re Armbruster 185 USPQ 204 (CCPA 1985) and Angstadt et al. , 190 USPQ 152 (CCPA 1990).

Therefore, the specification has failed to support enablement for the method for treating and/or preventing the above mental diseases. Therefore, an appropriate correction is required.

The following is a quotation of the second paragraph of 35 U.S.C. 112:

The specification shall conclude with one or more claims particularly pointing out and distinctly claiming the subject matter which the applicant regards as his invention.

Claims 1-11 are rejected under 35 U.S.C. 112, second paragraph, as being indefinite for failing to particularly point out and distinctly claim the subject matter which applicant regards as the invention.

In claims 1 and 7-8, the phrase "an obvious chemical equivalent" is recited. The expression is vague and indefinite because the specification does not specify what the obvious chemical equivalent may be for the compounds of the formula(I). Therefore, an appropriate correction is required.

In claims 4 and 7, the phrase "one of its variants or mutants" is recited. The expression is vague and indefinite because the specification does not specify what the

one of its variants or mutants may be for the *Cryphonectria parasitica*, DSM 14453.

Therefore, an appropriate correction is required.

In claim 7, the phrase " where appropriate into a physiologically tolerated salts" is recited. The expression is vague and indefinite because the specification does not specify when it is appropriate to convert the compounds of the formula (I) into the physiologically tolerated salt. Therefore, an appropriate correction is required.

Claim 8 recites the limitation " a compound of the formula (I)" in " an effective amount of a compound of the formula (I)". There is insufficient antecedent basis for this limitation in the claim.

### ***Claim Rejections - 35 USC § 102***

The following is a quotation of the appropriate paragraphs of 35 U.S.C. 102 that form the basis for the rejections under this section made in this Office action:

A person shall be entitled to a patent unless –

(b) the invention was patented or described in a printed publication in this or a foreign country or in public use or on sale in this country, more than one year prior to the date of application for patent in the United States.

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Claim 11 is rejected under 35 U.S.C. 102(b) as being anticipated clearly by the German collection of Microorganisms and Cell cultures (DSMZ\_Deutsche Sammlung von Mikroorganismen und Zellkulturen 8/29/2001).

DSMZ discloses the microorganism strain: *Cryphonectria parasitica*, DSM 14453 (see page 4 ,lines 1-8 of the specification).

This is identical with the claim.

Any inquiry concerning this communication or earlier communications from the examiner should be directed to Taylor Victor Oh whose telephone number is 571-272-0689. The examiner can normally be reached on 8:30-5:00.

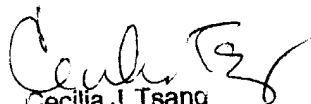
If attempts to reach the examiner by telephone are unsuccessful, the examiner's supervisor, Cecilia Tsang can be reached on 571-272-0562. The fax phone number for the organization where this application or proceeding is assigned is 703-872-9306.



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Information regarding the status of an application may be obtained from the Patent Application Information Retrieval (PAIR) system. Status information for published applications may be obtained from either Private PAIR or Public PAIR. Status information for unpublished applications is available through Private PAIR only. For more information about the PAIR system, see <http://pair-direct.uspto.gov>. Should you have questions on access to the Private PAIR system, contact the Electronic Business Center (EBC) at 866-217-9197 (toll-free).

*Myth* ✓ *gh*  
11/12/54

  
Cecilia J. Tsang  
**Supervisory Patent Examiner**  
**Technology Center 1600**